

What is claimed is:

1. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person; and

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice.

2. The method of claim 1, further comprising the steps of:

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and

(f) storing answers submitted by the person or caregiver in the database.

3. The method of claim 2, further comprising the step of :

(g) accessing the information stored along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

4. The method of claim 1, wherein the questionnaire includes criteria specified by a sponsor of the clinical study for determining whether the person is an eligible subject for the given clinical study.

5. The method of claim 1, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site.

6. The method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site.

7. The method of claim 1, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver.

8. The method of claim 1, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver.

15. The method of claim 1, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

16. A method for identifying subjects eligible to participate in a clinical study, comprising the steps of:

- (a) accessing a computer database that stores information about a plurality of persons; wherein for each of said plurality listed in the database, the database includes a geographic location of the person, an age and a gender of the person, and disease conditions of interest to the person;
- (b) submitting a query to the database, wherein the query includes criteria that reflect eligibility characteristics for persons suitable for participation as subjects in the clinical study; and
- (c) identifying de-identified data records of persons likely to be subjects eligible for the clinical study based on the query.

17. The method of claim 16, further comprising the steps of:

- (d) evaluating a feasibility of the clinical study based on the result of step (c);
- (e) exploring the feasibility of the clinical study by modifying the criteria and repeating steps (b)-(d) using the modified criteria.

18. The method of claim 16 or 17, wherein step (b) includes querying a therapeutic incidence area database.

25. The method of claim 16 or 17, wherein the criteria that reflect eligibility characteristics include inclusion/exclusion criteria for the clinical study.
26. An integrated on-line interactive forum that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subjects, comprising:
 - (a) an investigator database that contains information suitable for identification of qualified investigators for clinical studies sponsored by the sponsors;
 - (b) a subject database that contains information suitable for identification of eligible subjects for clinical studies sponsored by the sponsors; and
 - (c) an extranet coupled to the investigator database and the subject database that allows sponsors and investigators to securely exchange documents required to launch a clinical study.
27. The forum of claim 26, further comprising one or more web pages that provide information describing clinical studies to potential clinical study subjects and permit potential clinical study subjects to register for inclusion in the subject database.
28. The forum of claim 26 or 27, wherein privacy is protected by denying sponsors access to identifying information stored in the subject database.
29. The forum of claim 28, wherein the identifying information is provided to the qualified investigators for potential subjects in a clinical study.

30. The forum of claim 26 or 27, wherein a web server is used for identifying potential subjects for clinical studies.

31. The forum of claim 26 or 27, wherein a web server is used for identifying qualified investigators for clinical studies.

32. The forum of claim 26 or 27 further including a therapeutic incidence area database.

33. The forum of claim of 27 wherein the extranet and the one or more web pages are accessed using different URLs.

34. The forum of claim 26 further comprising a website coupled to the extranet that includes content available online for training clinical study investigators.

35. The forum of claim 27 further comprising a website coupled to the extranet that includes content available from online for training clinical study investigators.

36. The forum of claim 26 further comprising a link from the subject database to an electronic data capture company.

37. The forum of claim 27 further comprising a link from the subject database to an electronic data capture company.

38. The forum of claim 26 or 27 further comprising a link to the subject database from an electronic medical records company.

39. The forum of claim 26 or 27 further comprising a study listing database.

40. A method for identifying a qualified investigator to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores a geographic location of each of a plurality of investigators; wherein the database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the clinical study; and

wherein the qualified investigator is identified from the database based on the query and in accordance with the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

41. A method for identifying a qualified investigator to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores a geographic location of each of a plurality of investigators; wherein the database also stores a geographic location of subjects for the study;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the clinical study; and

wherein the qualified investigator is identified from the database based on the query and in accordance with the geographic location of subjects for the study.

42. The method of claim 41 wherein the database also stores an incidence or a prevalence of each of a plurality of disease conditions in each of a plurality of different geographic locations; and wherein the qualified investigator is identified from the database also based on the incidence or prevalence of the selected disease condition in the geographic location of the qualified investigator.

43. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to the prescription writing history of the investigator with respect to a plurality of medications; and

wherein the database also stores information that associates each of the medications with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's prescription writing history.

44. The method of claim 43 wherein the prescription writing history of the investigator is provided by the investigator to the database.

45. The method of claim 43 wherein the prescription writing history of the investigator is provided by a party other than the investigator to the data.

46. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to a history of laboratory procedure requests made by the investigator; and

wherein the database also stores information that associates each of the historical laboratory procedure requests with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's historical laboratory request information.

47. The method of claim 46 wherein the investigator's historical laboratory procedure results are provided by the investigator to the database.

48. The method of claim 46 wherein the investigator's historical laboratory procedure results are provided by a party other the investigator to the database.

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the given investigator's medical specialty.

53. The method of claim 52 wherein the investigator's medical specialty information is provided by the investigator to the database.

54. The method of claim 52 wherein the investigator's medical specialty is provided by a party other the investigator to the database.

55. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to experience of a medical staff of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the experience of the medical staff of the qualified investigator's medical specialty.

56. The method of claim 55 wherein the information regarding experience of the investigator's medical staff information is provided by the investigator to the database.

57. The method of claim 55 wherein the information regarding experience of the investigator's medical staff information is provided by a party other the investigator to the database.

58. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to how many clinical studies have been performed by the investigator;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with how many clinical studies have been performed by the qualified investigator.

59. The method of claim 58 wherein the information corresponding to how many clinical studies have been performed by the investigator is provided by the investigator to the database.

60. The method of claim 59 wherein the information corresponding to how many clinical studies have been performed by the investigator is provided by a party other the investigator to the database.

61. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

- (a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to hospital affiliations of the investigator; and
- (b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's hospital affiliations.

62. The method of claim 61 wherein the investigator's hospital affiliations information is provided by the investigator to the database.

63. The method of claim 61 wherein the investigator's hospital affiliations is provided by a party other the investigator to the database.

64. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

- (a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to a number of beds in hospital affiliations of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the number of beds in hospital affiliation of the qualified investigator.

65. The method of claim 64 wherein the number of beds in hospital affiliations of the investigator is provided by the investigator to the database.

66. The method of claim 64 wherein the number of beds in hospital affiliations of the investigator is provided by a party other the investigator to the database.

67. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to insurance provider affiliations of the investigator; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the insurance provider affiliations of the qualified investigator.

wherein the database also stores information that associates the PRF affiliations with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's PRF affiliations.

77. The method of claim 76 wherein the investigator's PRF affiliations information is provided by the investigator to the database.

78. The method of claim 76 wherein the investigator's PRF affiliation information is provided by a party other the investigator to the database.

79. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to equipment of the investigator; and

wherein the database also stores information that associates the equipment of the investigator with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the equipment of the qualified investigator.

80. The method of claim 79 wherein the investigator's equipment information is provided by the investigator to the database.

81. The method of claim 79 wherein the investigator's equipment information is provided by a party other the investigator to the database.

82. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to the investigator's practice setting; and

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's practice setting.

83. The method of claim 82 wherein the investigator's practice setting information is provided by the investigator to the database.

wherein a qualified investigator is identified from the database based on the query and in accordance with the qualified investigator's name.

87. The method of claim 86 wherein the investigator's medical specialty information is provided by the investigator to the database.

88. The method of claims 43, 44, or 45 wherein the query further includes search criteria selected from the group consisting of, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to the medical specialty of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each

investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

94. The method of claims 61, 62, or 63 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of

disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

95. The method of claims 64, 65, or 66 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

101. The method of claims 82 or 83 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's city and state of practice, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

102. The method of claims 84 or 85 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical studies, information corresponding to experience of a medical staff of the investigator, information corresponding to experience of a medical staff of the investigator, information corresponding to how many clinical studies have been performed by the investigator, information corresponding to hospital affiliations of the investigator, information corresponding to insurance provider affiliations of the investigator, information corresponding to mandated IRB relationships of the investigator, information corresponding to regulatory agency audits of the investigator, information corresponding to PRF affiliations of the investigator, information corresponding to equipment of the investigator, information corresponding to the investigator's practice setting, investigator information corresponding to services performed at the investigator hospital affiliates, information corresponding to investigator laboratory results, information corresponding to the geographic location of subjects of the investigators, information corresponding to the incidence or prevalence of each of a plurality of disease conditions in each of a plurality of types at geographic locations, and information corresponding to claims and information corresponding to the investigator's name.

103. The method of claims 86 or 87 wherein the query further includes search criteria selected from the group consisting of the prescription writing history of the investigator with respect to a plurality of medications, information corresponding to a history of laboratory requests made by the investigator, information corresponding to past participation of the investigator in clinical

- (c) obtaining permission from the person to send information regarding drugs, medical devices or medical therapies;
- (d) building the database by repeating steps (a) through (c); and
- (e) generating a list for use in marketing drugs, medical devices and medical therapies to persons by querying the database using criteria associated with the drugs, medical devices or medical therapies.

105. The method of claim 104, further comprising the steps of:

- (f) automatically determining, in accordance with the registration and permission information, whether to provide the person with notice of a clinical study associated with a disease condition of interest to the person;
- (g) automatically presenting a questionnaire associated with the given clinical study to the person; and
- (h) storing answers submitted by the person in the database.

106. The method of claim 104, further comprising the step of sending information to persons on the list regarding a drug, medical device and medical therapy.

107. A method of maintaining the confidentiality of clinical study information associated with each of a plurality of clinical study sponsors, comprising the steps of:

- (a) receiving said clinical study information from said plurality of clinical study sponsors; and
- (b) storing said clinical study information in a database;

wherein each sponsor is permitted full access to said clinical study information submitted by that sponsor and only aggregated access to information submitted by other sponsors.

108. The method of claim 107 wherein said clinical study information comprises at least one of investigator information, sponsor identification, protocol information, drug indication information, drug class information, clinical study enrollment goal information, actual clinical study enrollment information, and clinically evaluable subjects information.

109. The method of claim 108 wherein each sponsor is denied access to said protocol information, said drug class information and said sponsor identification information of other sponsors.

110. A method for ranking a clinical investigator, comprising the steps of:

(a) selecting at least two ranking criteria from the group consisting of investigator experience, professional certification, scientific leadership, regulatory audits and study coordinator experience; and

(b) determining the ranking for the clinical investigator by generating a composite ranking score from the at least two ranking criteria.

111. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators;

wherein a data record is stored for each investigator listed in the database and includes information corresponding to a history of laboratory results of the investigator; and

wherein the database also stores information that associates each of the laboratory results with one or more disease conditions;

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(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a given investigator is identified from the database based on the query and in accordance with the given investigator's historical laboratory results information.

112. The method of claim 111 wherein the history of laboratory results of the investigator is provided by the investigator to the database.

113. The method of claim 111 wherein the history of laboratory results of the investigator is provided by a party other than the investigator to the database.

114. A method for identifying investigators qualified to perform a clinical study, comprising the steps of:

(a) accessing a computer database that stores information on a plurality of investigators; wherein a data record is stored for each investigator listed in the database and includes information corresponding to services performed in hospital affiliations of the investigator; and wherein the database also stores information that associates the services performed in hospital affiliations with one or more disease conditions;

(b) submitting a query to the database, wherein the query includes information representing a selected disease condition associated with the study; and wherein a qualified investigator is identified from the database based on the query and in accordance with the services performed in hospital affiliations of the qualified investigator.

120. The method of claim 107 wherein the aggregated access provides a lesser degree of detail of said information.

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